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April 5, 2004

CERTIFICATE OF MAILING
37 C.F.R. § 1.8

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April 5, 2004 — Date
Robert E. Hanson

MAIL STOP APPEAL BRIEF-PATENTS
Commissioner for Patents
P. O. Box 1450
Alexandria, VA 22313-1450

RE: *SN 09/606,808 "TRANSFORMABLE INBRED CORN LINE LIZL5 AND METHODS OF USE THEREOF" - James R. Larkins et al.*
Our Ref.: DEKA:264US; Client Ref. [34-63(51675)]

Commissioner:

Transmitted herewith for filing are:

1. Reply Brief (original and 2 copies);

2. A return postcard to acknowledge receipt of these materials. Please date stamp and mail this postcard.

It is believed that no fees under 37 C.F.R. §§ 1.16 to 1.21 are occasioned by the filing of this paper; however, should the Commissioner determine otherwise, the Commissioner is hereby authorized to deduct said fees from Fulbright & Jaworski Deposit Account No. 50-1212/DEKA:264US.

Respectfully submitted,

Robert E. Hanson
Reg. No. 42,628

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PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:
James R. Larkins et al.

Serial No.: 09/606,808

Filed: June 28, 2000

For: TRANSFORMABLE INBRED CORN LINE LIZL5 AND METHODS FOR USE THEREOF

Group Art Unit: 1638

Examiner: Mehta, A.

Atty. Dkt. No.: DEKA:264/REH

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REPLY BRIEF

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REPLY BRIEF

Mail Stop Appeal Brief-Patents
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

Appellants hereby submit an original and two copies of this Reply Brief in response to the Examiner's Answer, dated February 5, 2004. No fees are believed due in connection with this paper; however, should any fees be due the Commissioner is authorized to withdraw the appropriate fees from Fulbright & Jaworski Deposit Account No. 50-1212/DEKA:264US.

Please date stamp and return the enclosed postcard to evidence receipt of this document.

I. REAL PARTIES IN INTEREST

The real party in interest is Monsanto Company, the parent of wholly-owned subsidiary DeKalb Genetics Corporation, the assignee of this application.

II. RELATED APPEALS AND INTERFERENCES

Appeals were filed in U.S. Patent Application Ser. No. 09/771,938; U.S. Patent Application Ser. No. 09/772,520; U.S. Patent Application Ser. No. 09/788,334; U.S. Patent Application Ser. No. 10/077,589; and U.S. Patent Application Ser. No. 10/077,591. The cases are not related to the current case but share the same Real Parties in Interest, are also directed to inbred corn plants, and present many of the same issues on appeal as this case and therefore may have a bearing on the Board's decision in the pending appeal.

III. STATUS OF THE CLAIMS

Claims 1-39 were filed with the original application. Claims 1-39 were pending at the time of the Fourth Office Action mailed July 16, 2003. Claims 1, 4-6 and 18-21 were allowed in the Fourth Office Action and claims 2, 3, and 7-17 and 22-39 were rejected. The current Appeal is of the rejection of claims 2, 3, 7-17 and 22-39 in the Fourth Office Action. A copy of the appealed claims is attached as Appendix 1 and a copy of the pending claims is attached as Appendix 2.

IV. STATUS OF AMENDMENTS

No amendments were made subsequent to the Final Office Action or the Fourth Office Action.

V. SUMMARY OF THE INVENTION

The invention relates to the novel inbred corn plant designated LIZL5 and seeds or populations of seed thereof. Specification at page 5, lines 8-22. The invention also relates to single locus converted plants of LIZL5. Specification at page 6, lines 8-21. The invention further relates to methods for breeding LIZL5 with other corn plants, and hybrid plants produced thereby. Specification from page 7, line 6 to page 8, line 2. The invention still further relates to methods of transforming corn plant LIZL5 and the plants made thereby. Specification at page 9, lines 3-17.

VI. ISSUE ON APPEAL

(A) Are claims 2, 3, 7-17, 25-28 and 37-39 properly rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicants regard as the invention?

(B) Are claims 14-17 and 22-39 properly rejected under 35 U.S.C. §112, first paragraph, as not being supported by an adequate written description in the specification?

(C) Are claims 25-39 properly rejected under 35 U.S.C. §112, first paragraph, as not being enabled?

VII. GROUPING OF THE CLAIMS

The claims have been rejected for an alleged indefiniteness, lack of written description and enablement. Each of the appealed claims are directed to separate or progressively narrow embodiments of the invention. Different issues are thus raised for each of the claims under written description and enablement. The claims therefore stand or fall separately for purposes of the instant appeal.

VIII. SUMMARY OF THE ARGUMENT

A large number of distinct indefiniteness rejections were issued. The indefiniteness rejections were made without reference to the general principle that all that is necessary under the second paragraph of 35 U.S.C. § 112 is that one of skill in the art understand what is claimed in view of the specification. The claims fully satisfy this requirement and thus the rejections are without merit.

The claims have also been rejected as lacking an adequate written description. However, Appellants have fully described the claimed subject matter. Each of the claimed hybrid plants and seeds having inbred corn plant LIZL5 as one parent have as half of their genome the same genetic contribution from LIZL5, given that corn plant LIZL5 is inbred. These plants therefore share this structural characteristic. The shared structural characteristic is fully described in the specification by way of the detailed descriptions in the specification and the biological deposit of seed of LIZL5. Single locus conversions of LIZL5 and LIZL5 transformed with a transgene are also fully described in the specification by way of the description of LIZL5 and added traits.

The Examiner has rejected the claims as allegedly not being enabled for production of single locus conversions and transformation of LIZL5. The rejection ignores working examples in the specification describing the production of exemplary single locus converted plants. The techniques are applicable to any transgene, all that is required is genetic transformation and/or multiple generations of backcrossing. The specification describes this and other techniques in great detail, fully enabling the claimed subject matter. The Examiner has nonetheless issued the rejection based solely on references having no applicability to maize. The rejection has also been made for an alleged failure to disclose "all" transgenes that could possibly be used.

However, this is not required for enablement. Appellants have disclosed more than a representative number of transgenes. The claims are thus fully enabled.

IX. REPLY

The Examiner's Answer contains a substantial reiteration of the arguments previously presented and briefed. Appellants have responded where further clarification is necessary in view of the Examiner's Answer.

A. The Indefiniteness Rejections Are Premised on a Misapplication of the Standard Under 35 U.S.C. §112, Second Paragraph

Appellants submit that the Examiner has failed to apply the correct standard for an indefiniteness rejection. The Examiner's Answer throughout indicates that the claims have not been given a reasonable reading, in context, as one of skill in the art would view them when in possession of the specification. The Examiner in particular appears to require absolute certainty of claim terms when read in isolation and by those with no skill in the art. This is not the correct standard. Viewed properly, the claim terms are fully definite.

The Federal Circuit has repeatedly made clear that absolute certainty in a claim is not required. The test for definiteness under 35 U.S.C. 112, second paragraph, is whether "those skilled in the art would understand what is claimed when the claim is read in light of the specification." *Orthokinetics, Inc. v. Safety Travel Chairs, Inc.*, 806 F.2d 1565, 1576, 1 USPQ2d 1081, 1088 (Fed. Cir. 1986). The Examiner must consider the claim as a whole to determine whether the claim apprises one of ordinary skill in the art of its scope. *See, e.g., Solomon v. Kimberly-Clark Corp.*, 216 F.3d 1372, 1379, 55 USPQ2d 1279, 1283 (Fed. Cir. 2000). This has not been done here.

As explained in detail in the Appeal Brief, all of the claim terms have a well known meaning in the art when viewed in the context of the claim and with reference to the specification. Reversal of the rejections is thus respectfully requested.

B. The Written Description Rejections Are Improper

The written description rejections are premised on the legally incorrect position that an applicant must show both a structure *and* a function for the structure in order to satisfy written description. For example, on page 24 the Examiner's Answer discounts the fact that claimed hybrid plants share the genetic complement of variety LIZL5 because: "[t]hat all hybrids will inherit half of their alleles from LIZL5 does not provide any information concerning the morphological and physiological characteristics that will be expressed by the claimed hybrids." This misconception is continued throughout.

The correct legal standard does not require a structure and a function when the structure provided describes the claimed invention. Rather, an applicant must merely describe the claimed subject matter by "whatever characteristics sufficiently distinguish it." *Amgen v. Chugai Pharmaceutical*, 927 F.2d 1200, 1206 (Fed. Cir. 1991). Here, the same genetic complement of parent plant LIZL5 is contained in all of the claimed hybrids and describes and distinguishes the hybrid plants in full compliance with §112. This constitutes a description of concrete, distinguishable structural characteristics shared by all of the hybrid plants. This fully satisfies written description because what second parent contributes the other half of the genome is irrelevant to the production of a hybrid plant. As stated by the Examiner at page 34 in the context of single locus conversions "there is only one genetic structure that is relevant." What is relevant here is the genetic complement of variety LIZL5, which was fully described.

The hybrids are further described because one of skill in the arty would immediately envision such plants. First, the entire genetic complement of corn variety LIZL5 was described

by biological deposit pursuant to the *Enzo* holding. Second, the identity of the second plant is irrelevant to whether a hybrid is produced. Third, thousands of corn plants that could serve as a second parent are well known to those of skill in the art, including several hundred having issued U.S. patents and biological deposits with the ATCC. Based on the seed deposits, those of skill in the art would immediately envision at least hundreds of hybrid plants down to the level of the DNA sequence of the plant genome. Given this detail of description the morphological traits are completely superfluous.

The fact that this description is made at the genetic level rather than by morphological traits in no way negatives written description. Written description is satisfied by describing structure characteristics allowing those of skill in the art to immediately "visualize or recognize the identity of the members of the genus. *The Regents of The University of California v. Eli Lilly and Co.*, 119 F.3d 1559, 1568; 43 USPQ2d 1398, 1406 (Fed. Cir. 1997). Appellants have done precisely this by disclosing the genome of corn plant LIZL5 that is included in each of the claimed hybrid plants.

C. Rejection of Claims Under 35 U.S.C. §112, First Paragraph - Enablement

The Examiner continues to assert the enablement rejection based on the contention that: (1) several references from species other than corn indicate difficulty in preparing single locus conversions, and (2) all single locus traits were not known and/or the corresponding phenotypic traits were not shown.

With regard to the first point, Appellants note that none of the references have been shown to have any relevance to *corn* plants. Hunsperger deals with petunias; Kraft with sugar beets and Eshed with Tomatoes. The relevance of the references to the claimed invention has therefore not been established as is specifically required to establish a *prima facie* case of non-

enablement. Appellants pointed this out in the Appeal Brief, but the Answer simply disagrees without providing a basis for doing so.

Appellants submit that the position taken is incorrect because corn breeding is extremely advanced and well known in the art as evidenced by the descriptions in the specification and references cited therein. This is due in large part to the fact that corn is one of the world's major food crops and largest seed crops. As explained in the specification, North American farmers alone plant ***tens of millions of acres*** of corn at the present time and there are ***extensive national and international commercial corn breeding*** programs. The market for corn seed in the U.S. alone is in excess of $2 billion (e.g., http://www.biotech-info.net/Distribution_benefits.pdf). No basis has been shown to conclude that the same is true of the other plants and it is respectfully submitted that this is not true. The cited references therefore have not been shown to have any relevance to the claims.

The Examiner has also not provided any basis other than opinion to suggest why the genetics of any of petunias, sugar beets or tomatoes are relevant to corn. Each of these plants are widely genetically diverged from maize – they are each classified as dicotyledonous plants whereas maize is a monocotyledonous plants. This distinction was noted by the Federal Circuit in *Plant Genetic Systems v. DeKalb Genetics Corp.*, in which a finding on non-enablement was affirmed because the claims read on both monocotyledonous and dicotyledonous plants, but were only enabled for dicotyledonous plants. 315 F.3d 1335 (Fed. Cir. 2003).

It therefore appears that the Examiner has improperly placed the burden to show enablement on Appellants. The indication that the references concerning petunias, sugar beets and tomatoes apply to corn is made without any support. At the same time, the Examiner attempts to require Appellants to show why this is not true. While Appellants have nonetheless

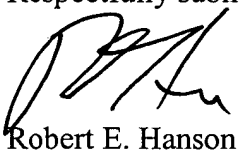
done so, it is respectfully notes that it is the ***Office*** that bears the burden of supporting its rejections. Appellants submit that this has not been done.

With regard to the particular gene, Applicants have already shown over two pages well more than a representative number of genes for creation of single locus conversions. Further, the Examiner has provided no basis to indicate why the particular single locus used is relevant to production of the conversion. Introduction of DNA into a cell occurs without regard to the nucleic acid transformed. Using the well known procedures described in detail in the specification essentially any conversion can routinely be made. Appellants therefore submit that the current rejection is unsupported in fact or law. Reversal of the rejection is therefore respectfully requested.

X. CONCLUSION

It is respectfully submitted, in light of the above, none of the pending claims lack written description. Therefore, Appellants request that the Board reverse the pending grounds for rejection.

Respectfully submitted,



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Date: April 5, 2004

APPENDIX 1: APPEALED CLAIMS

2. The inbred corn seed of claim 1, further defined as an essentially homogeneous population of inbred corn seed.

3. The inbred corn seed of claim 1, further defined as essentially free from hybrid seed.

7. An essentially homogeneous population of corn plants produced by growing the seed of the inbred corn plant LIZL5, a sample of said seed having been deposited under ATCC Accession No. PTA-2192.

8. A corn plant capable of expressing all the physiological and morphological characteristics of the inbred corn plant LIZL5, a sample of the seed of said inbred corn plant LIZL5 having been deposited under ATCC Accession No. PTA-2192.

9. The corn plant of claim 8, further comprising a cytoplasmic or nuclear gene conferring male sterility.

10. A tissue culture of regenerable cells of inbred corn plant LIZL5, wherein the tissue regenerates plants capable of expressing all the physiological and morphological characteristics of the inbred corn plant LIZL5, a sample of the seed of said inbred corn plant LIZL5 having been deposited under ATCC Accession No. PTA-2192.

11. The tissue culture of claim 10, wherein the regenerable cells comprise cells derived from embryos, immature embryos, meristematic cells, immature tassels, microspores, pollen, leaves, anthers, roots, root tips, silk, flowers, kernels, ears, cobs, husks, or stalks.

12. The tissue culture of claim 11, wherein the regenerable cells are in the form of protoplasts or callus.

13. A corn plant regenerated from the tissue culture of claim 10, wherein said corn plant is capable of expressing all of the physiological and morphological characteristics of the inbred

corn plant designated LIZL5, a sample of the seed of said inbred corn plant designated LIZL5 having been deposited under ATCC Accession No. PTA-2192.

14. An inbred corn plant cell of the corn plant of claim 8, said cell comprising:
    (a) an RFLP genetic marker profile in accordance with the profile shown in Table 6; or
    (b) a genetic isozyme typing profile in accordance with the profile shown in Table 7.

15. A corn seed comprising the inbred corn plant cell of claim 14.

16. A tissue culture comprising the inbred corn plant cell of claim 14.

17. The inbred corn plant of claim 8, comprising:
    (a) an RFLP genetic marker profile in accordance with the profile shown in Table 6; or
    (b) a genetic isozyme typing profile in accordance with the profile shown in Table 7.

22. Hybrid corn seed produced by the process of claim 20.

23. A corn plant produced by the process of claim 21.

24. The corn plant of claim 23, wherein the plant is a first generation (F_1) hybrid corn plant.

25. The corn plant of claim 4, further comprising a single locus conversion.

26. The corn plant of claim 25, wherein the single locus was stably inserted into a corn genome by transformation.

27. The corn plant of claim 25, wherein the locus is selected from the group consisting of a dominant allele and a recessive allele.

28. The corn plant of claim 25, wherein the locus confers a trait selected from the group consisting of herbicide resistance, insect resistance, resistance to bacterial, fungal, nematode or viral disease, yield enhancement, waxy starch, improved nutritional quality, enhanced yield stability, male sterility and restoration of male fertility.

29. A method of preparing a transgenic maize cell comprising:

a) providing cells of inbred corn plant LIZL5, a sample of the seed of the inbred LIZL5 having been deposited under ATCC Accession No. PTA-2192;

b) contacting said cells with a pre-selected DNA; and

c) identifying at least a first transgenic cell of inbred corn plant LIZL5 which has been transformed with said pre-selected DNA.

30. The method of claim 29, further comprising the step of:

d) regenerating a fertile transgenic plant from said transgenic cell.

31. The method of claim 29, wherein said contacting comprises a method selected from the group consisting of microprojectile bombardment, PEG mediated transformation of protoplasts, electroporation, silicon carbide fiber mediated transformation, or *Agrobacterium*-mediated transformation.

32. The method of claim 31, wherein said contacting comprises use of microprojectile bombardment.

33. The method of claim 31, wherein said contacting comprises use of PEG mediated transformation of protoplasts.

34. The method of claim 31, wherein said contacting comprises use of electroporation.

35. The method of claim 31, wherein said contacting comprises use of silicon carbide fiber mediated transformation.

36. The method of claim 31, wherein said contacting comprises use of *Agrobacterium*-mediated transformation.

37. A fertile transgenic maize plant preparable by the process of claim 30.

38. A seed of the fertile transgenic maize plant of claim 37, wherein said seed comprises said pre-selected DNA.

39. A plant grown from the seed of claim 38, said plant comprising said pre-selected DNA.

APPENDIX 2: PENDING CLAIMS

1. Inbred corn seed of the corn plant LIZL5, a sample of said seed having been deposited under ATCC Accession No. PTA-2192.

2. The inbred corn seed of claim 1, further defined as an essentially homogeneous population of inbred corn seed.

3. The inbred corn seed of claim 1, further defined as essentially free from hybrid seed.

4. An inbred corn plant produced by growing the seed of the inbred corn plant LIZL5, a sample of said seed having been deposited under ATCC Accession No. PTA-2192.

5. Pollen of the plant of claim 4.

6. An ovule of the plant of claim 4.

7. An essentially homogeneous population of corn plants produced by growing the seed of the inbred corn plant LIZL5, a sample of said seed having been deposited under ATCC Accession No. PTA-2192.

8. A corn plant capable of expressing all the physiological and morphological characteristics of the inbred corn plant LIZL5, a sample of the seed of said inbred corn plant LIZL5 having been deposited under ATCC Accession No. PTA-2192.

9. The corn plant of claim 8, further comprising a cytoplasmic or nuclear gene conferring male sterility.

10. A tissue culture of regenerable cells of inbred corn plant LIZL5, wherein the tissue regenerates plants capable of expressing all the physiological and morphological characteristics

of the inbred corn plant LIZL5, a sample of the seed of said inbred corn plant LIZL5 having been deposited under ATCC Accession No. PTA-2192.

11. The tissue culture of claim 10, wherein the regenerable cells comprise cells derived from embryos, immature embryos, meristematic cells, immature tassels, microspores, pollen, leaves, anthers, roots, root tips, silk, flowers, kernels, ears, cobs, husks, or stalks.

12. The tissue culture of claim 11, wherein the regenerable cells are in the form of protoplasts or callus.

13. A corn plant regenerated from the tissue culture of claim 10, wherein said corn plant is capable of expressing all of the physiological and morphological characteristics of the inbred corn plant designated LIZL5, a sample of the seed of said inbred corn plant designated LIZL5 having been deposited under ATCC Accession No. PTA-2192.

14. An inbred corn plant cell of the corn plant of claim 8, said cell comprising:

(a) an RFLP genetic marker profile in accordance with the profile shown in Table 6; or

(b) a genetic isozyme typing profile in accordance with the profile shown in Table 7.

15. A corn seed comprising the inbred corn plant cell of claim 14.

16. A tissue culture comprising the inbred corn plant cell of claim 14.

17. The inbred corn plant of claim 8, comprising:

(a) an RFLP genetic marker profile in accordance with the profile shown in Table 6; or

(b) a genetic isozyme typing profile in accordance with the profile shown in Table 7.

18. A process of producing corn seed, comprising crossing a first parent corn plant with a second parent corn plant, wherein said first or second corn plant is the inbred corn plant LIZL5, a

sample of the seed of said inbred corn plant LIZL5 having been deposited under ATCC Accession No. PTA-2192, wherein seed is allowed to form.

19. The process of claim 18, further defined as a process of producing hybrid corn seed, comprising crossing a first inbred corn plant with a second, distinct inbred corn plant, wherein said first inbred corn plant is the inbred corn plant LIZL5, a sample of the seed of said inbred corn plant LIZL5 having been deposited under ATCC Accession No. PTA-2192.

20. The process of claim 19, wherein crossing comprises the steps of:

(a) planting in pollinating proximity seeds of said first and second inbred corn plants;

(b) cultivating the seeds of said first and second inbred corn plants into plants that bear flowers;

(c) emasculating the male flowers of said first or second inbred corn plant to produce an emasculated corn plant;

(d) allowing cross-pollination to occur between said first and second inbred corn plants; and

(e) harvesting seeds produced on said emasculated corn plant.

21. The process of claim 20, further comprising growing said harvested seed to produce a hybrid corn plant.

22. Hybrid corn seed produced by the process of claim 20.

23. A corn plant produced by the process of claim 21.

24. The corn plant of claim 23, wherein the plant is a first generation (F_1) hybrid corn plant.

25. The corn plant of claim 4, further comprising a single locus conversion.

26. The corn plant of claim 25, wherein the single locus was stably inserted into a corn genome by transformation.

27. The corn plant of claim 25, wherein the locus is selected from the group consisting of a dominant allele and a recessive allele.

28. The corn plant of claim 25, wherein the locus confers a trait selected from the group consisting of herbicide resistance, insect resistance, resistance to bacterial, fungal, nematode or viral disease, yield enhancement, waxy starch, improved nutritional quality, enhanced yield stability, male sterility and restoration of male fertility.

29. A method of preparing a transgenic maize cell comprising:

a) providing cells of inbred corn plant LIZL5, a sample of the seed of the inbred LIZL5 having been deposited under ATCC Accession No. PTA-2192;

b) contacting said cells with a pre-selected DNA; and

c) identifying at least a first transgenic cell of inbred corn plant LIZL5 which has been transformed with said pre-selected DNA.

30. The method of claim 29, further comprising the step of:

d) regenerating a fertile transgenic plant from said transgenic cell.

31. The method of claim 29, wherein said contacting comprises a method selected from the group consisting of microprojectile bombardment, PEG mediated transformation of protoplasts, electroporation, silicon carbide fiber mediated transformation, or *Agrobacterium*-mediated transformation.

32. The method of claim 31, wherein said contacting comprises use of microprojectile bombardment.

33. The method of claim 31, wherein said contacting comprises use of PEG mediated transformation of protoplasts.

34. The method of claim 31, wherein said contacting comprises use of electroporation.

35. The method of claim 31, wherein said contacting comprises use of silicon carbide fiber mediated transformation.

36. The method of claim 31, wherein said contacting comprises use of *Agrobacterium*-mediated transformation.

37. A fertile transgenic maize plant preparable by the process of claim 30.

38. A seed of the fertile transgenic maize plant of claim 37, wherein said seed comprises said pre-selected DNA.

39. A plant grown from the seed of claim 38, said plant comprising said pre-selected DNA.